

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA LP, AKTIEBOLAGET)	
DRACO, KBI INC. and KBI-E INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 08-305 (JJF)
)	
BARR LABORATORIES, INC., and)	
BARR PHARMACEUTICALS, INC.,)	
)	
Defendants.)	

PLAINTIFFS' REPLY TO COUNTERCLAIMS

Plaintiffs AstraZeneca LP, Aktiebolaget Draco, KBI Inc., and KBI-E Inc., by their attorneys, reply to the numbered paragraphs the Counterclaims of Defendant Barr Laboratories, Inc. as follows:

1. Plaintiffs admit the allegations of paragraph 1, on information and belief.
2. Plaintiffs admit the allegations of paragraph 2.
3. Plaintiffs admit the allegations of paragraph 3.
4. Plaintiffs admit the allegations of paragraph 4.
5. Plaintiffs admit the allegations of paragraph 5.
6. Plaintiffs admit that Defendants' counterclaims purport to seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 and 21 U.S.C. 355(j)(5)(C).
7. Plaintiffs admit the allegations of paragraph 7.
8. Plaintiffs do not contest that the Court has personal jurisdiction over them for the limited purpose of this litigation. The remaining allegations of Paragraph 8 are denied.
9. Plaintiffs do not contest that the Court has personal jurisdiction over them for the limited purpose of this litigation. The remaining allegations of Paragraph 9 are denied.

10. Plaintiffs do not contest venue in this Court for the limited purpose of this litigation.

11. Paragraph 11 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

12. Paragraph 12 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

13. Paragraph 13 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

14. Paragraph 14 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

15. Paragraph 15 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

16. Paragraph 16 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

17. Paragraph 17 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

18. Paragraph 18 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

19. Paragraph 19 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

20. Paragraph 20 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

21. Paragraph 21 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

22. Paragraph 22 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

23. Paragraph 23 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

24. Paragraph 24 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

25. Paragraph 25 states a legal conclusion to which no response is required. To the extent that a response is required, the allegations are denied.

26. In response to Paragraph 26, Plaintiffs state that Aktiebolaget Draco is the owner of U.S. Patent No. 6,423,340 (the “‘340 patent”) and U.S. Patent No. 5,643,602 (the “‘602 patent”), and KBI and KBI-E have rights in the United States under the ‘340 patent and the ‘602 patent. The remaining allegations of Paragraph 26 are denied.

27. Plaintiffs admit that Barr Laboratories filed with the FDA an ANDA with a certification pursuant to Section 505(j)(2)(B)(i) of the FDCA, 21 U.S.C. 355(j)(2)(A)(vii)(IV) (“Paragraph IV certification”) to obtain approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of ENTOCORT® EC. The remaining allegations of Paragraph 27 are denied.

28. In response to Paragraph 28, Plaintiffs admit that on or about April 11, 2008, AstraZeneca LP and Aktiebolaget Draco received a letter dated April 9, 2008, stating that Barr Laboratories had filed with the FDA an ANDA seeking approval to manufacture, use, offer for sale, and sell a generic version of ENTOCORT® EC. The letter purports to notify

AstraZeneca LP and Aktiebolaget Draco that Barr's ANDA was submitted with a Paragraph IV certification that Barr's manufacture, use or sale of the Barr ANDA product will not infringe any claims of the '340 patent or the '602 patent, that the '340 patent and the '602 patent are invalid, and/or that the '340 patent and the '602 patent are unenforceable. The letter purports to contain an Offer of Confidential Access to Barr's ANDA. Plaintiffs admit that they filed a patent lawsuit against Barr on May 22, 2008 and that Barr was served with Plaintiffs' Complaint on May 23, 2008. Plaintiffs state that their Complaint asserts that Barr has infringed the '340 and '602 patents under 35 U.S.C. § 271(e)(2)(A) and that the commercial manufacture, use, sale, offer to sell, or importation of the Barr ANDA product will infringe the '340 and '602 patents. The remaining allegations of Paragraph 28 are denied.

29. Plaintiffs admit the allegations of paragraph 29.

30. Plaintiffs admit that the '340 patent is entitled "Method For The Treatment of Inflammatory Bowel Diseases" and refer to the patent for what it discloses.

31. Plaintiffs admit that they have sued Barr for infringing the '340 patent, and there is an actual case and controversy between Barr and the Plaintiffs as to Barr's infringement. The remaining allegations of Paragraph 31 are denied.

32. Plaintiffs admit the allegations of paragraph 32.

33. Plaintiffs admit that the '602 patent is entitled "Oral Composition For The Treatment of Inflammatory Bowel Diseases" and refer to the patent for what it discloses.

34. Plaintiffs admit that they have sued Barr for infringing the '602 patent, and there is an actual case and controversy between Barr and the Plaintiffs as to Barr's infringement. The remaining allegations of Paragraph 34 are denied.

35. Plaintiffs deny the allegations of Paragraph 35.

36. Plaintiffs restate and incorporate by reference their answers to paragraphs 1 through 35 as if fully set forth herein.

37. Plaintiffs deny the allegations of Paragraph 37.

38. Plaintiffs restate and incorporate by reference their answers to paragraphs 1 through 37 as if fully set forth herein.

39. Plaintiffs deny the allegations of Paragraph 39.

40. Plaintiffs restate and incorporate by reference their answers to paragraphs 1 through 39 as if fully set forth herein.

41. Plaintiffs deny the allegations of Paragraph 41.

42. Plaintiffs restate and incorporate by reference their answers to paragraphs 1 through 41 as if fully set forth herein.

43. Plaintiffs deny the allegations of Paragraph 43.

RELIEF

44. Plaintiffs deny that Barr is entitled to any of the relief it has requested or any other relief, and deny that Barr is entitled to a trial by jury.

45. Any allegation contained in Barr's Answer, Affirmative Defenses, Counterclaims, and Prayer for Relief that is not specifically admitted is denied.

PLAINTIFFS' AFFIRMATIVE DEFENSES

46. Barr's Counterclaims are barred in whole or in part because they fail to state a cause of action for which relief may be granted.

47. Barr's Counterclaims are barred on the basis of any additional defenses or counterclaims that discovery may reveal.

PLAINTIFFS' PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek the following relief:

- A. A judgment dismissing with prejudice Barr's Counterclaims;
- B. A finding that this is an exceptional case, and an award of attorneys' fees to Plaintiffs pursuant to 35 U.S.C. § 285;
- C. An award of costs and expenses of Plaintiffs in defending these Counterclaims; and
- D. Such further and other relief as this Court determines to be just and proper.

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July 7, 2008

CERTIFICATE OF SERVICE

I, Jack B. Blumenfeld, hereby certify that on July 7, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

John C. Phillips, Jr., Esquire
PHILLIPS, GOLDMAN & SPENCE, P.A.


I also certify that copies were caused to be served on July 7, 2008 upon the following in the manner indicated:

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